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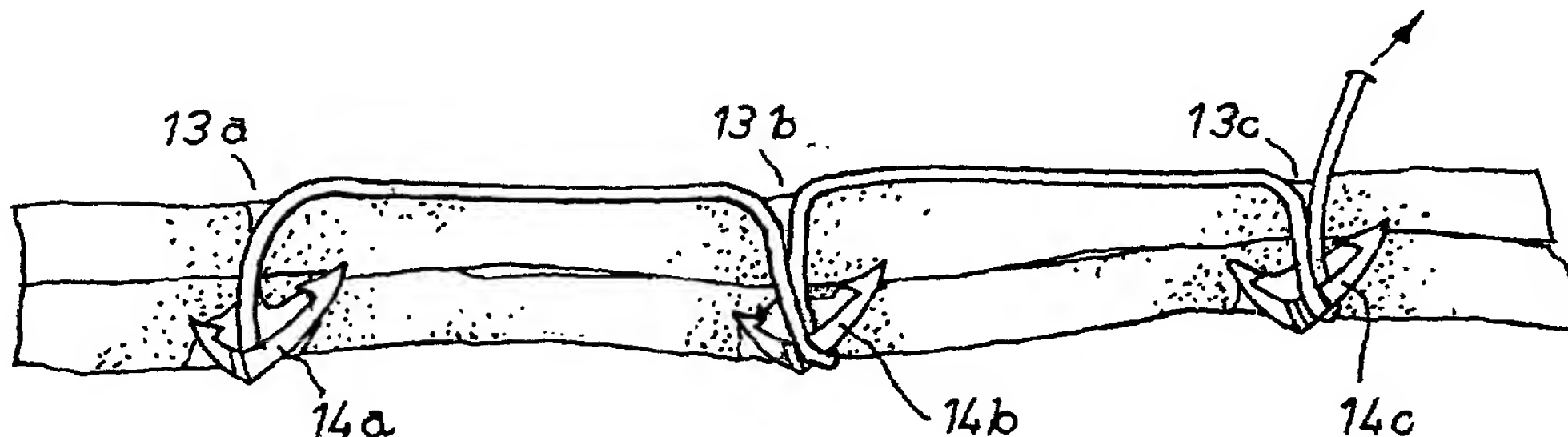
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(54) Title: METHOD AND APPARATUS FOR STITCHIN



(57) Abstract: Method and Apparatus for Stitching There is disclosed a method for stitching, comprising penetrating a material to be stitched, delivering through the penetration an anchor, securing a first end of a thread by the anchor in the penetration, penetrating the material in a position spaced from the first penetration, delivering through the second penetration a second anchor, attaching the thread through the second penetration by the second anchor to the material, repeating the procedure as often as required until a final penetration, at which a final anchor is delivered and a second end of the thread secured by the final anchor thereto.



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Method and Apparatus for Stitching

This invention relates to stitching, particularly, but not exclusively, to surgical suturing.

5

Material, e.g. soft tissue layers, can be stitched, or sutured, using thread which is passed through the tissue using a needle, as in conventional hand sewing, and knotted. As an alternative, also in surgery, staples are used. Each has its place. Conventional thread suturing is usually no problem for a skilled surgeon when the suturing site is readily accessible. In endoscopic procedures, however, where access is restricted, conventional stitching, and particularly knotting, is difficult. Staples are relatively easy to deploy, but have their own drawbacks, principally that they can misfire and migrate, and, being easy to deploy, tend to be overused, which may necessitate further surgical recovery procedures.

15

The present invention provides methods and apparatus for stitching which are of use in surgery, but which may also be useful in other areas, for example in textile stitching.

The invention comprises, in one aspect, a method for stitching, comprising penetrating a material to be stitched, delivering through the penetration an anchor, securing a first end of a thread by the anchor in the penetration, penetrating the material in a position spaced from the first penetration, delivering through the second penetration a second anchor, attaching the thread through the second penetration by the second anchor to the material, repeating the procedure as often as required until a final penetration, at which a final anchor is delivered and a second end of the thread secured by the final anchor thereto.

25

The anchors may be threaded on the thread. If they are loosely threaded, free to move along the thread, the spacing between penetrations may be chosen at will.

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Penetration may be effected by a piercing element, An anchor delivery element delivers, at each penetration, an anchor through the material. After each penetration, the piercing and delivery elements may be withdrawn, leaving a length of thread through the penetration, secured on the anchor. A predetermined tension may be applied to the
5 thread at each penetration to effect a desired tightness.

An embedding action may then follow to embed the anchor in the material. The embedding action may comprise a rotation, which may be through 180°. The embedding action may comprise a pulling action.

10

The anchor may be barbed, the better to retain it in its embedded position.

After the last anchor has been delivered, the thread may be severed.

15 A stitching tool may hold a plurality of anchors, the anchor delivery element advancing anchors one by one to successive penetrations.

The method may be used in surgery, and may be used for fixing soft tissue to soft tissue, or soft tissue to bone, in which case at least one suture may be implantable in bone. Two
20 anchors may be implanted into bone through soft tissue to be fixed thereto, the suture thread extending between them being tightened to hold the tissue against the bone. Anchors with attached threads are already known primarily for fixing tissue to bone, though with the possibility of fixing tissue to tissue, see, for example, US 6 024 758 and EP 1 199 036. As in those publications, the bone may be pre-drilled for the anchor.

25

The invention also comprises an anchor and thread assembly for use in the methods herein proposed, comprising a thread and a plurality of eyed anchors threaded thereon. The thread may be a surgical suture thread, and the anchors bio-compatible.

- 3 -

The invention also comprises an anchor for an assembly as proposed, having a hook-like configuration, having a barb at at least one end and an eye for a thread. The anchor may be made of a bio-compatible material, which may be a bio-absorbable material, such as an absorbable polymer such as polylactic acid or a copolymer of PGA-co-TMC or of
5 PGA-co-PCL.

The anchor may, however, be made of metal or a non-absorbable polymer such as acetal.

The anchor may comprise a releasable biological factor, such as a drug, an antibiotic or
10 an inducer or trigger for a natural healing factor.

The invention also comprises a stitching implement comprising an anchor reservoir for a plurality of anchors, a thread reservoir for a thread and a piercing implement operative to penetrate material to be stitched and an anchor delivery implement to deliver through
15 the penetration one of said anchors with attached thread, the stitching implement being adapted to withdraw the delivery element and piercing implement from the penetration, leaving the anchor, and to repeat the procedure at spaced apart locations along the material.

20 The anchor reservoir may comprise a slideway on which anchors can be stacked, rather like staples in a stapler. The thread reservoir may comprise a spool holder. The anchor and thread reservoirs may hold a plurality of anchors threaded on a thread held in the thread reservoir.

25 The stitching implement may have a thread cutting knife, which may be extendable from the region of the thread and anchor reservoir into an operative position.

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The stitching implement may be fashioned as an endoscopic surgical device, and may comprise an anchor indexing mechanism and a thread tension defining system operable from a handpiece.

5 Methods of stitching, especially in surgery, an anchor, an anchor and thread assembly and a stitching implement will now be described with reference to the accompanying drawings, in which:

10 Figure 1 is a view of a surgical site at which a stitching implement according to the invention is deployed;

Figure 2 is a diagrammatic depiction of steps 1 to 14 in a suturing procedure approximating soft tissues;

15 Figure 3 is a cross section showing the suturing extending over three penetrations;

Figure 4 is a lengthwise section through a stitching implement; and

20 Figure 5 is a view of anchors assembled on a thread for deployment by the implement of Figure 4.

The drawings illustrate a method, using a stitching implement 10, for stitching comprising penetrating a material - in this case, soft tissues 11, 12 to be approximated - delivering through the penetration 13a an anchor 14a, securing a first end of a thread 25 15 by the anchor 14a in the penetration 13a, penetrating the material 11, 12 in a position 16 spaced from the first penetration 13a, delivering through the second penetration 13b, at position 16, a second anchor 14b, attaching the thread 15 through the second penetration 13b by the second anchor 14b to the material 11, 12, repeating the procedure

- 5 -

as often as required until a final penetration 13c, at which a final anchor 14c is delivered and a second end of the thread secured by the final anchor 14c thereto.

Figure 3 illustrates suturing extending over the three penetrations 13a, 13b, 13c.

5

As seen in Figure 5, the anchors 14 are threaded on the thread 15, having eyes 14e for this purpose. The first anchor 14a is attached, as by a knot (as illustrated), or by a suitable adhesive, or by injection moulding or in any other appropriate fashion, to the first end of the thread 15.. The other anchors are free to slide on the thread 15. The
10 anchors 14 have barbs 21 at each end.

Penetration is effected by a piercing element 17. An anchor delivery element 18 delivers, at each penetration, an anchor 14 through the material. In the case of surgical suturing, of course, the piercing element 17 will actually bore through the tissues 11, 12. In other
15 cases, the material may be pre-penetrated.

Figure 2, Step 1, shows the piercing implement 17 projecting from the end of the stitching implement 10 to a preset depth set by a mechanism 118 (Figure 4) in the handpiece 10a of the implement 10. Step 2 shows penetration by the piercing element
20 17. And Step 3 shows implantation of an anchor 14a, with thread 15 attached, by the delivery element 18, which is operated by an actuator 18a in the handpiece 10a. Step 4 shows the anchor 14a - which has a sharp leading edge 19 to extend the penetration - fully through the penetration. In Step 5, the whole implement 10 has been axially rotated through 180° by the surgeon, placing the barb 21 against a part of the tissue 12 that has
25 not been damaged by the penetration and effectively wrapping the thread about the anchor so as to secure it frictionally, and in Step 6, the implement 10 has been pulled back to embed the anchor 14 in the tissue. Step 7 shows the anchor delivery element 18 withdrawn from the penetration, leaving the anchor 14a behind, embedded in the tissue. Next, at Step 8, the implement 10 is pulled back, allowing a length of thread 15 to be

- 6 -

unwound from the spool (shown here diagrammatically - in fact, it will be in the handpiece).

The implement 10 is now rotated back through 180° , and moved along to the next
5 penetration site - Step 9.. In Step 10, another penetration has been effected, and, in
Step 11, excess thread 15 is pulled back by the spool. In Step 12, the implement 10 is
again rotated to place the barb against undamaged tissue. Step 13 is essentially a
repetition of Steps 6 and 7. In Step 14, the implement is fully withdrawn again, ready for
the next penetration. At the end of the procedure, the thread 15 is cut, and the implement
10 fully withdrawn. An extendable knife, not shown, may be deployed from the implement
to sever the thread 15, or a knife or other device may be deployed through another portal
at the surgical site.

The facility to pull thread back means that even separated soft tissues can be drawn
15 together, as when a section has been excised - the thread can simply be "reeled in" to
approximate the tissues. For this, the implement need not be rotated, or rotated only
slightly less than the 180° , at each penetration, to reduce the frictional resistance to the
thread passing through the anchors

20 Figure 1 illustrates a typical surgical site for endoscopic surgery having a number of
portals through which devices can be inserted, including a laparoscope 9 and the stitching
implement 10.

Figure 4 shows one embodiment of stitching implement 10 in cross-section, comprising
25 a handpiece 10a, an anchor reservoir 41 for a plurality of anchors 14, a thread reservoir
comprising a spool holder 42, a piercing element 17 with a depth setting actuator 17a,
and an anchor delivery element 18 which has a formation at its end 18a which releasably
engages an anchor. The piercing implement and the delivery element can be withdrawn
back into the implement 10, the delivery element engaging the next in line anchor 14.

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The implement 10 can be configured as a handpiece 10a with an attachable cassette 10b holding the supply of anchors and thread. The handpiece 10a will have various actuators and controls, such as the thread tension control and rods, perhaps with spring return features, to extend the piercing implement and the delivery element, as well as the suture
5 cutting knife, if provided. The piercing implement may, of course, be adapted to cut the suture.

Laparoscopic surgical procedures in which the stitching method can be used effectively include Collis-Nissen Fundoplication, Palliative side-to-side Esophagogastrostomy, End-
10 to-end Anastomosis, Fascia Closure and Ileal "J" Pouch procedures.

Tissue can be fixed to bone using anchors as taught in the US and EP references mentioned above, or any other suitable anchoring devices such as screws located in pre-drilled bores in the bone.

CLAIMS

- 1 A method for stitching, comprising penetrating a material to be stitched,
delivering through the penetration an anchor, securing a first end of a thread by the
5 anchor in the penetration, penetrating the material in a position spaced from the first
penetration, delivering through the second penetration a second anchor, attaching the
thread through the second penetration by the second anchor to the material, repeating the
procedure as often as required until a final penetration, at which a final anchor is
delivered and a second end of the thread secured by the final anchor thereto.
- 10
- 2 A method according to claim 1, in which the anchors are threaded on the
thread.
- 3 A method according to claim 1 or claim 2, in which the penetration is
15 effected by a piercing element.
- 4 A method according to any one of claims 1 to 3, in which an anchor is
delivered through a penetration by an anchor delivery element.
- 20 5 A method according to claim 4, in which, after each penetration, the
piercing and delivery elements are withdrawn, leaving a length of thread through the
penetration secured to the anchor.
- 6 A method according to any one of claims 1 to 5, in which the stitching
25 implement effects an embedding action to embed the anchor in the material.
- 7 A method according to claim 6, in which the embedding action comprises
a rotation of the implement.

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8 A method according to claim 7, in which the rotation is through 180°.

9 A method according to claim 7 or claim 8, in which the embedding action
comprises a pulling action.

5

10 A method according to any one of claims 1 to 9, in which the anchor is
barbed.

11 A method according to any one of claims 1 to 10, in which, after the last
10 anchor has been delivered, the thread is severed.

12 A method according to any one of claims 1 to 11, in which a stitching tool
holds a plurality of anchors, an anchor delivery element advancing anchors one by one
to successive penetrations.

15

13 A method according to any one of claims 1 to 12, used in surgery.

14 A method according to claim 13, used for fixing soft tissue to soft tissue.

20 15 A method according to claim 14, in which separated soft tissue sections are
approximated by pulling in the thread.

16 A method according to claim 13, used for fixing soft tissue to bone.

25 17 A method according to claim 16, in which at least one anchor is implanted
in the bone.

- 10 -

18 A method according to claim 17, in which two anchors are implanted into bone through soft tissue to be fixed thereto and the suture thread extending between them tightened to hold the tissue against the bone.

5 19 A method according to claim 17 or claim 18, in which the bone is pre-drilled for the anchors.

20 An anchor and thread assembly for use in a method according to any one of claims 1 to 19, comprising a thread and a plurality of eyed anchors threaded thereon.
10

21 An assembly according to claim 20, of which the thread is a surgical suture thread and the anchors are bio-compatible.

22 An assembly according to claim 19 or claim 20, provided in a cassette for
15 attachment to a handpiece forming a stitching implement.

23 An anchor for an assembly according to any one of claims 20 to 22, having a hook-like configuration having a barb at at least one end and an eye for a thread.

20 24 An anchors according to claim 23, made of bio-compatible material.

25 An anchor according to claim 24, made of a bio-absorbable material.

26 An anchors according to claim 25, made of an absorbable polymer such as
25 polylactic acid or a co-polymer of PGA-co-TMC or of PGA-co-PCL.

27 An anchor according to claim 23, made of metal.

- 11 -

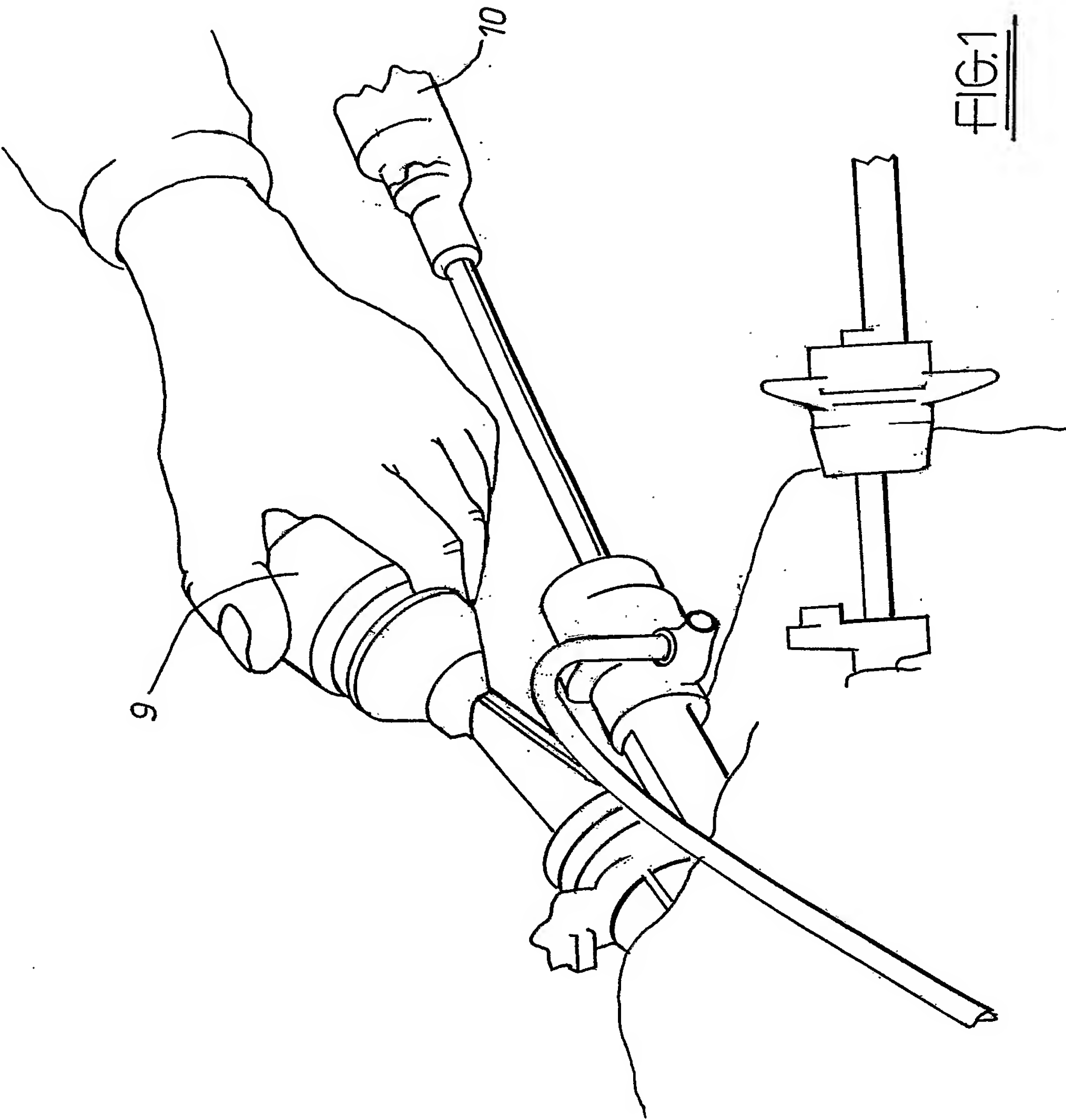
- 28 An anchor according to claim 23, made of a non-absorbable polymer such as acetal.
- 29 An anchor according to any one of claims 23 to 28, comprising a releasable
5 biological factor.
- 30 An anchor according to claim 29, including a drug.
- 31 An anchors according to claim 29 or claim 30, including an antibiotic.
10
- 32 An anchor according to any one of claims 29 to 31, including an inducer or trigger for a natural healing factor.
- 33 A stitching implement comprising an anchor reservoir for a plurality of
15 anchors and a thread reservoir for a thread and a piercing implement operative to penetrate material to be stitched and an anchor delivery element to deliver through a penetration one of said plurality of anchors with attached thread, the stitching implement being adapted to withdraw the piercing implement from the penetration, leaving the anchor, and to repeat the procedure at spaced apart locations along the material.
20
- 34 An implement according to claim 33, in which the anchor reservoir comprises a slideway on which anchors can be stacked.
- 35 An implement according to claim 33 or claim 34, in which the thread
25 reservoir comprises a spool holder.
- 36 An implement according to any one of claims 33 to 35, in which the anchor and thread reservoirs hold a plurality of anchor threads on a thread held in the thread reservoir.

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37 An implement according to any one of claims 33 to 36, comprising a thread cutting knife extendable from the region of the thread and anchor reservoirs.

38 An implement according to any one of claims 33 to 37, fashioned as an
5 endoscopic surgical device.

39 An implement according to claim 38, comprising an anchor indexing mechanism and a thread tension defining system operable from a handpiece.



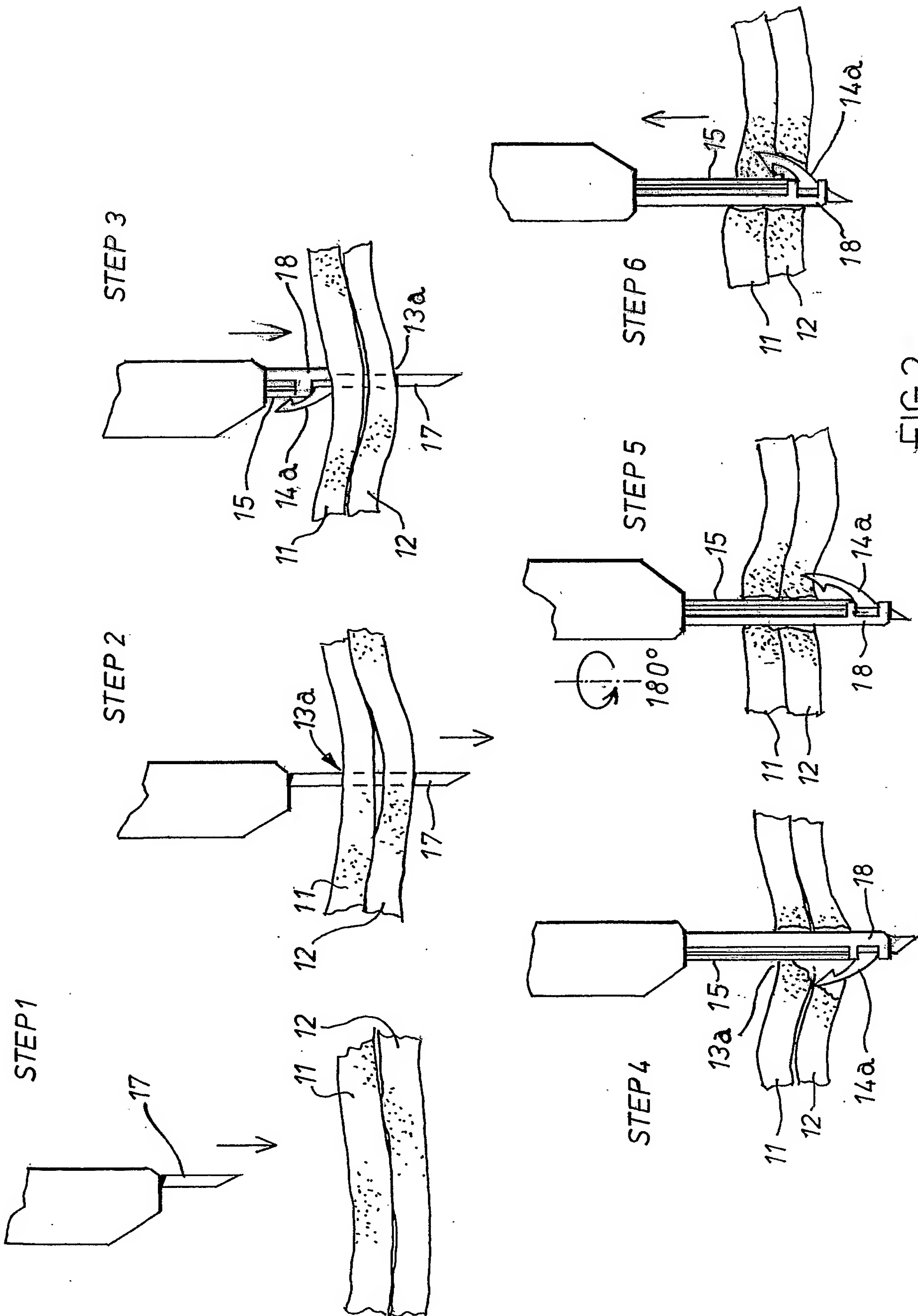
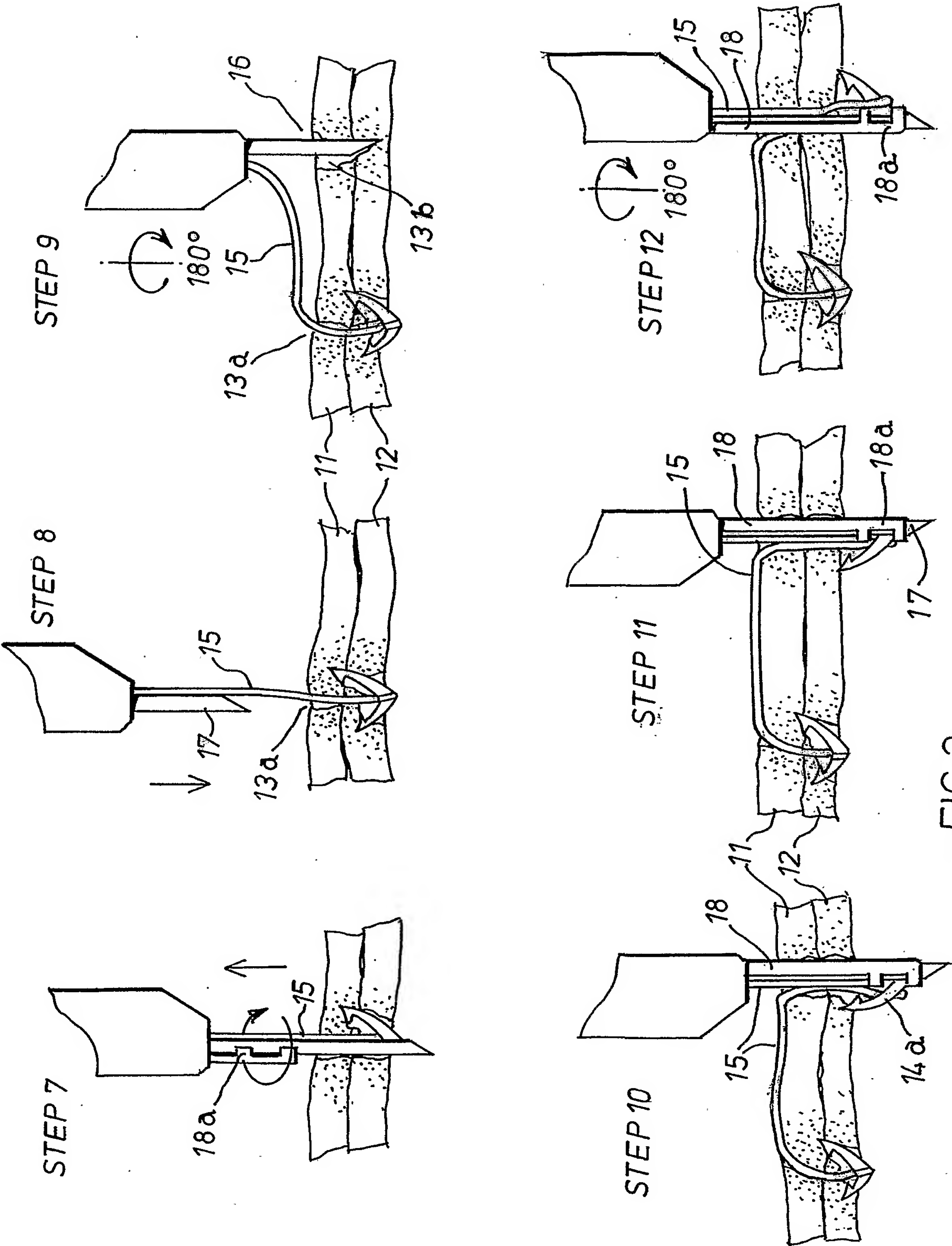
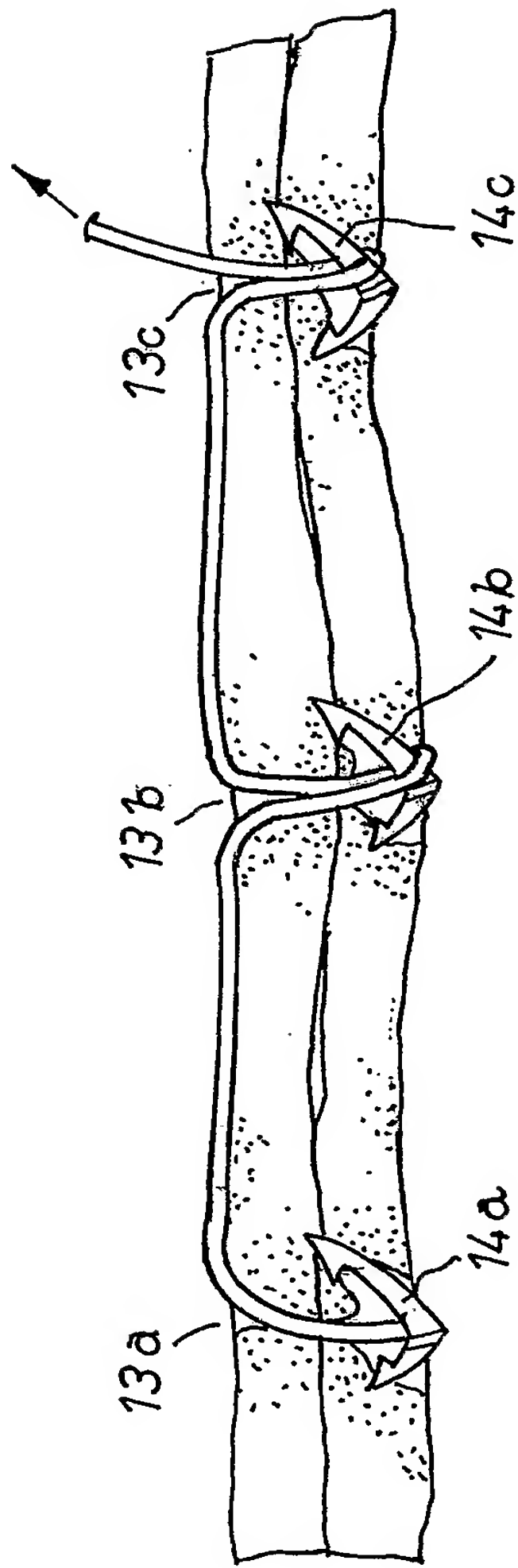
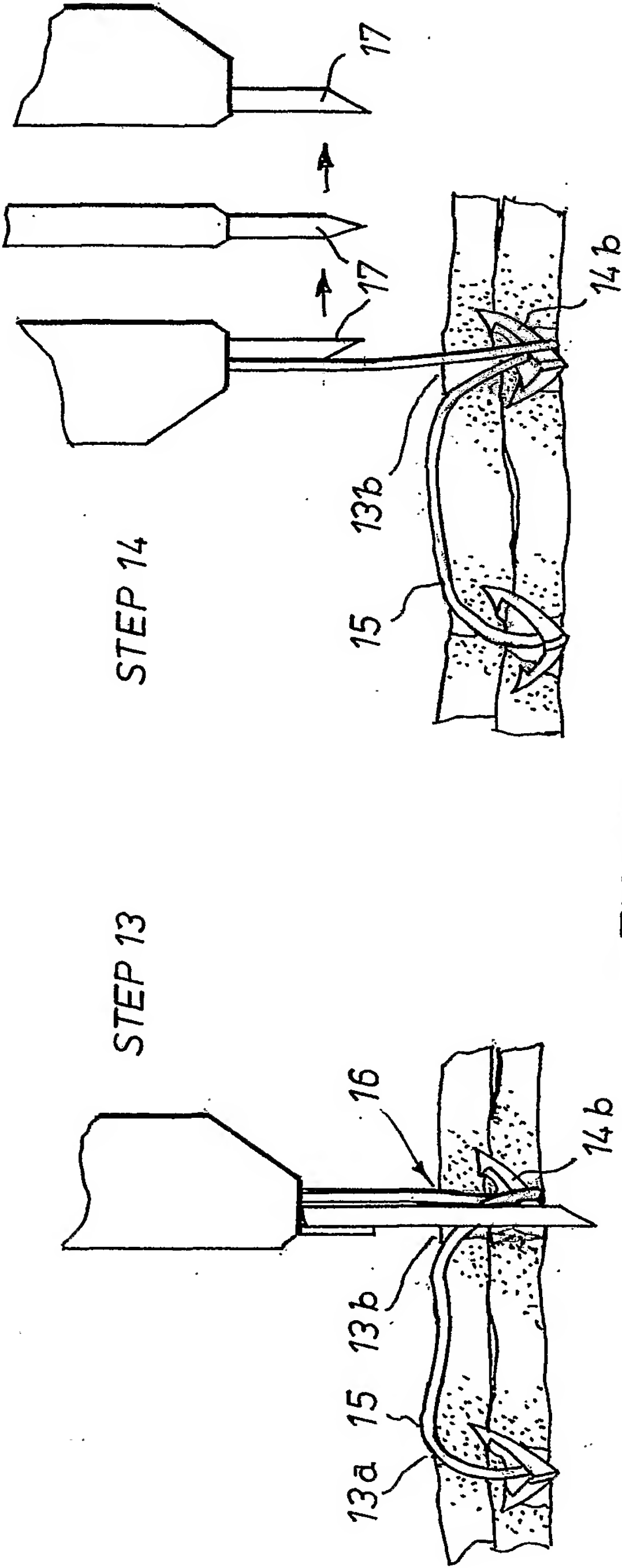
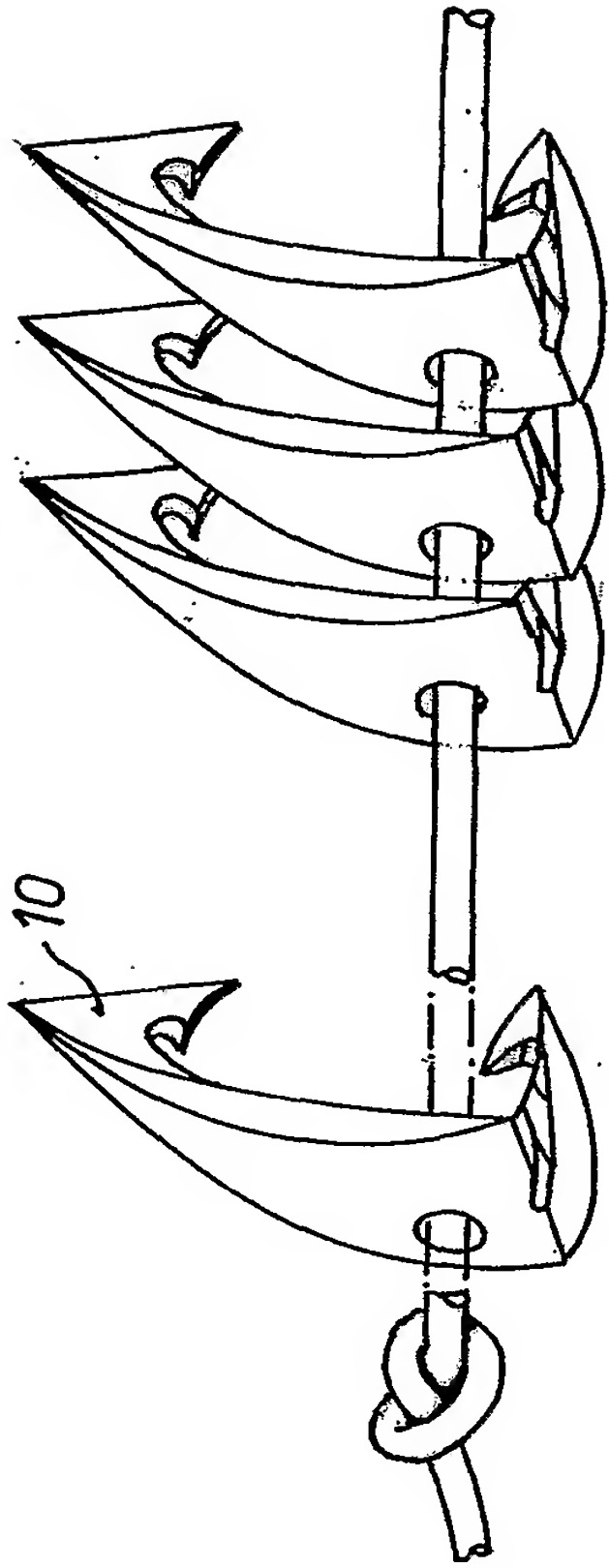
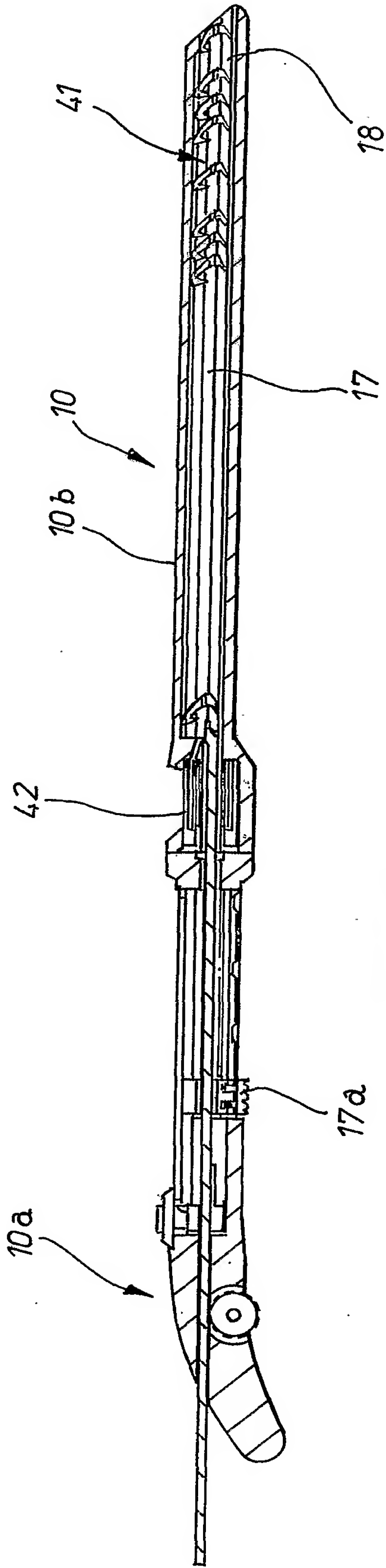


FIG. 2







INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 891 168 A (THAL RAYMOND) 6 April 1999 (1999-04-06) column 4, line 33 -column 5, line 21; figure 2 ---	1,2,6, 10,13, 14, 16-21, 23,26
A	US 5 549 631 A (BONUTTI PETER M) 27 August 1996 (1996-08-27) figure 4 column 4, line 5 -column 5, line 25; figures 8-12 --- -/--	1,2,4,6, 12-15, 20,33, 34,36,38

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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8 November 2002

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PCT/GB 02/03086

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 01 39671 A (SMITH & NEPHEW INC) 7 June 2001 (2001-06-07) claim 1; figures 4-5D ---	1-6, 11-18, 20, 23-26, 33, 34
P, X	DE 100 19 922 A (CO DON AG ; R J G STORZ GMBH (DE)) 25 October 2001 (2001-10-25) column 2, line 56 -column 3, line 63; figures 1-6 -----	1-39

INTERNATIONAL SEARCH REPORT

PCT/GB 02/03086

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5891168	A	06-04-1999	US 5709708 A	20-01-1998
			AU 714085 B2	16-12-1999
			AU 3820097 A	25-08-1998
			EP 0951237 A1	27-10-1999
			JP 2001509711 T	24-07-2001
			WO 9833439 A1	06-08-1998
<hr/>				
US 5549631	A	27-08-1996	US 5464426 A	07-11-1995
			US 5403348 A	04-04-1995
			US 5549630 A	27-08-1996
			US 5534012 A	09-07-1996
			US 5569305 A	29-10-1996
			US 5584862 A	17-12-1996
			US RE36974 E	28-11-2000
			US 6056773 A	02-05-2000
			US 5527343 A	18-06-1996
			US 6077292 A	20-06-2000
			US 5522846 A	04-06-1996
			US 5496348 A	05-03-1996
			US 6287325 B1	11-09-2001
			US 5733306 A	31-03-1998
			US 5845645 A	08-12-1998
			US 5941900 A	24-08-1999
<hr/>				
WO 0139671	A	07-06-2001	AU 1804501 A	12-06-2001
			WO 0139671 A1	07-06-2001
			US 2002019649 A1	14-02-2002
<hr/>				
DE 10019922	A	25-10-2001	DE 10019922 A1	25-10-2001
			AU 7237701 A	07-11-2001
			WO 0180746 A1	01-11-2001
			EP 1204377 A1	15-05-2002
<hr/>				